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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional): 50164/002002

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on September 21, 2005

Signature Rosemarie Perullo

Typed or printed name Rosemarie Perullo

Application Number	Filed
09/611,835	July 7, 2000

First Named Inventor: Brent R. Stockwell

Art Unit	Examiner
1639	My-Chau T. Tran

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

Customer No.: 21559

I am the

- [ ] applicant/inventor.
- [ ] assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- [x] attorney or agent of record. Registration number 30,162
- [ ] attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____

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Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

[x] *Total of 1 forms are submitted.

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Rosemarie Perullo
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Rosemarie Perullo
Signature of person mailing correspondence

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Brent R. Stockwell et al.	Art Unit:	1639
Serial No.:	09/611,835	Examiner:	My-Chau T. Tran
Filed:	July 7, 2000	Customer No.:	21559
Title:	METHODS FOR IDENTIFYING COMBINATIONS OF ENTITIES AS THERAPEUTICS		

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Commissioner for Patents
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PRE-APPEAL BRIEF REQUEST FOR REVIEW

I. Introduction

In the five years since this application was filed, numerous searches have been conducted by the PTO. All rejections over prior art references save one, Stylli (discussed below), have been overcome.

II. The Examiner in the Final Office Action made two clear errors:

1) The Examiner misread the reference, Stylli, that forms the basis for the obviousness rejection, and

2) The Examiner improperly rejected all of the claims over Stylli, despite the manifest absence of anything in Stylli suggesting or rendering obvious the inventions whose limitations are recited in the claims.

III. The Inventions

Claim 89 is directed to a fundamentally new and powerful idea: new pharmaceuticals can be identified by screening large numbers of combinations of compounds (such as FDA-approved drugs) for those few that exhibit a desirable pharmacological activity, such as anti-tumor activity. The assignee of the application has identified several new pharmaceuticals using the claimed method, including one (a combination of chlorpromazine and pentamidine), which assignee has patented, and which is now the subject of a clinical trial.

Patentable features are recited in other claims, independent and dependent. For example, independent claim 154 (discussed below) recites a screening method in which, prior to the combination screening step, individual drugs having desired activity are selected.

IV. The Final Office Action

All of the claims were rejected for obviousness over Stylli. The Examiner (referring to claim 89), while admitting that Stylli "does not expressly disclose that the chemical compounds tested are forty-nine unique combinations of seven different compounds" argues that Stylli does "hint at the claimed inventive concept of multi-

compound screening, i.e., screening a desired two or higher order combination of compounds."

In support of this assertion, the Examiner quotes a single sentence from Stylli: "[I]n practicing the methods of the invention, the products or compositions can be used alone or in combination with one another or in combination with other therapeutic or diagnostic agents." The Examiner misreads this sentence as teaching "screening a combination of compounds (see e.g. col. 44, lines 20-23)."

V. The Errors in the Final Action

1) The Examiner misread Stylli

Stylli does not teach screening combinations of compounds.

The quoted sentence from Stylli does not say what the Examiner says it does—that drug combinations can be screened. This is not a question of interpretation; the meaning of the sentence is entirely clear. In that sentence, following the subject "products or compositions," is a verb, "used." The verb "to use" is not a synonym for "to screen." The verb means "employed." The products of Stylli are, according to the cited sentence, "used," or employed, for some purpose, and that purpose is absolutely clear: <u>therapy</u>. The sentence is referring to <u>combination therapy</u>, the administration of a combination of drugs to a person, and not to combination screening. The "methods of the invention" referred to in the passage are <u>methods of treatment, not</u> methods of screening.

If further evidence of the obvious, incontrovertible fact that Stylli is referring only to combination therapy, not screening, were required, the context of the cited sentence provides such evidence. The title of the section of Stylli in which the cited sentence appears is

"Pharmaceutical Compositions" (column 43, line 45; emphasis supplied). The next thirteen paragraphs provide descriptions of various pharmaceutical compositions, dosages, and routes of administration. Indeed, the sentence preceding the one quoted by the Examiner is directed to factors associated with dosing, which pertains only to therapy, not screening.

2) The Examiner should have allowed claims 90-156

None of the limitations of claims 90-156, which are narrower in scope than claim 89, are taught or inherent in the only remaining prior art reference of record, Stylli. Furthermore, the Examiner has not pointed to any passages in Stylli that even arguably teach these limitations. Nor are the inventions of these claims obvious over Stylli, alone or combined with any other prior art references.

Several of these claims warrant discussion.

Claims 111 and 148 require that the screened compounds be FDA-approved small molecules. This innovative idea generated the aforementioned anti-cancer therapeutic, the chlorpromazine/pentamidine combination. Neither Stylli nor any other prior art reference suggests screening such compounds.

Claim 154, which is independent, recites a multi-step drug discovery process in which the first step involves contacting living test cells with at least 100 compounds; the compounds that cause a change in a biological property of the cells are then selected. The selected compounds, which have now been determined to have biological activity, are then screened, in combination, for biological activity. The assignee of the present application has employed this method to identify many effective combinations of drugs. Nothing in Stylii or any other prior art suggests or renders obvious this invention.

Conclusion

For all of the above-stated reasons, it is requested that the claims be allowed.